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14TH DISTRICT, TEXAS

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WESTERN HEMISPHERE

Congress of the United States
House of Representatives
Washington, DC 20515–4314

203 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225–2831

312 SOUTH MAIN
SUITE 228
VICTORIA, TX 77901
(361) 576–1231

200 WEST 2ND STREET
SUITE 210
FREEPORT, TX 77541
(979) 230–0000

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 106
Rockville, MD 20852

Dear Sir:

I am pleased to respond to the Food and Drug Administration (FDA)'s request for comments regarding ways in which the FDA can ensure that its regulations do not conflict with the First Amendment. Considering the FDA's history of promulgating overly restrictive laws and policies limiting consumers' access to truthful health care information, I am very pleased to see the FDA address this issue. I hope this represents a new commitment on the part of the agency to ensure that its regulations do not infringe on consumers' right to truthful health information. After all, in a free society the presumption is always in favor of allowing consumers greater access to information.

I believe there are two specific policy changes the FDA should make in order to ensure the agency's actions do not infringe on legitimate First amendment interests. First, the FDA should liberally use disclaimers in order to ensure consumers are not denied information regarding the health benefits of foods and dietary supplements. Second, the FDA should return to the "more than a scintilla of evidence" standard for efficacy in the drug approval process.

I. The FDA should modify its regulations to allow for the liberal use of disclaimers which can be understood by the reasonably intelligent lay person

In 1998, the United States Court of Appeals for the District of Columbia ruled in *Pearson v. Shalala* that the Food and Drug Administration's (FDA) final rules prohibiting certain nutrient-disease relationship claims are invalid under the First amendment to the United States Constitution. Since the Supreme Court denied the FDA's petition of certiorari, the agency remains bound by *Pearson*'s decision. Yet, four years after this decision, and nearly ten years after Congress liberalized the regulations of dietary supplements in the Dietary Supplements and Health and Education Act (DSHEA), the FDA continues its attempts to censor legitimate health claims regarding the benefits of dietary supplements.

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One way the FDA could comply with the *Pearson* decision is to allow the use of disclaimers informing consumers that these health claims have not been approved by the FDA. As you are no doubt aware, the court in *Pearson* embraced this approach. However, the FDA should not impose overly complex or stringent regulations regarding the appropriate language for a disclaimer. Making companies jump through numerous regulatory hoops to approve disclaimer language could burden First Amendment rights. This approach would make *Pearson* a Pyrrhic victory for the First Amendment.

In order to comply with the spirit, as well as the letter of the *Pearson* decision, the FDA should ensure that disclaimers contain accurate information presented in a manner easily understood by a reasonably intelligent layman. This would allow the American people the widest possible access to truthful information regarding the health benefits of foods and dietary supplements without compromising the FDA's mission.

II. The FDA should use a "more than a scintilla of evidence" standard to evaluate the efficacy of drug claims

Another way the FDA could enhance First Amendment protections is by returning to the "more than a scintilla of evidence" standard of evaluating efficacy. In 1962, the FDA was granted the authority to evaluate effectiveness of drugs and medical devices in addition to evaluating safety. Initially, the FDA used a "more than a scintilla of evidence" standard, but subsequently imposed a higher standard of approval for efficacy claims.

An overly restrictive standard of measuring efficacy restricts access to products that pose no risk to human health. Instead, consumers are denied information about products simply because the product's performance does not meet the standards set by FDA bureaucrats. However, there is a necessary degree of subjectivity involved in determining efficacy; thus, any efficacy standards will be at least partially arbitrary. This is especially so considering that the same medicine can effect individuals differently. Denying consumers access to products that pose no risk to human health based on arbitrary standards certainly undermines the First Amendment.

By adopting a "more than a scintilla of evidence" standard for efficacy claims, the FDA would ensure consumers have the widest access to information regarding beneficial treatments and cures. A liberal standard would also allow patients to work with their health care providers to determine which medicines are effective in meeting patients' unique needs. In addition, using the "more than a scintilla" standard will help make available many effective treatments that American citizens are denied as well as lower the costs of FDA approval on manufacturers, and free up the FDA's resources to focus on legitimate risks to public health.

III. Conclusion

I want to once again thank the Food and Drug Administration for allowing this comment period on how to better ensure that the FDA's regulations respect the First Amendment rights of consumers. Hopefully, this represents a new era in FDA policy and a move away from the

overreaching paternalism that has violated both consumers' First Amendment interests and sound public health policy.

One of the best changes the FDA can make to ensure its regulations comply with the First amendment is to allow manufacturers of foods and dietary supplements to make unapproved health claims as long as those claims are accompanied by a disclaimer. Another important change is to reverse the standard of judging efficacy to "more than a scintilla." It is my hope that the FDA soon implements both of these recommendations. Thank you for your consideration of my views.

Sincerely,

Ron Paul

[redacted]

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House of Representatives
Washington, DC 20515–4314

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Ln Room ~~1547~~ 1061
Rockville, MD 20852

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